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## AUDIT REPORT FOR NETHERLANDS

October 1 through October 24, 2001

### INTRODUCTION

#### Background

This report reflects information that was obtained during an audit of the Netherlands meat inspection system from October 1 through October 24, 2001. Eight of the 24 establishments certified to export meat to the United States were audited. Four of these were slaughter establishments; the other four were conducting processing operations.

The last audit of the Dutch meat inspection system was conducted in February 2000. Eight establishments were audited: all were acceptable. During this new audit, three of these establishments were included in the new itinerary.

The major concerns from the previous audit were the following.

- No continuous coverage of inspection in processed product and warehouse/freezer facilities.
- Monthly supervisory visits were not performed. Only four internal reviews were conducted per year by district officials.
- No inspection coverage provided for second and third shift operations.
- There is no official oversight of private laboratories.
- No arsenic monitoring.
- *Salmonella* species testing started in May 1999. Following 1<sup>st</sup> and 2<sup>nd</sup> set-samples results failing the performance standards, further testing was put on hold until March 2000.
- RVV (National Inspection Service for Livestock and Meat) does not have a microbiological monitoring program for finished products, which includes 'scheduled' or 'directed' testing (*Salmonella* and *Listeria*) for ready-to-eat product.
- Dead on arrival (DOA) carcasses and condemned/inedible product was not denatured or de-characterized.
- Verification sampling for species identification is not done by RVV. The Netherlands is not exempt from official species verification.
- Post-mortem inspection procedures for large calves was incomplete.

The Netherlands exports only processed pork products to the United States. Product must be cooked (to at least 69° C), cured and dried (at least 90 days), or canned (shelf stable-sealed, then cooked). Fresh pork may not be imported due to APHIS restrictions, although OIE has declared Netherlands free of swine fever. Product prepared from beef of Netherlands origin is not eligible for export to U.S. due to bovine spongiform encephalopathy (BSE).

As of end of August 2001, Dutch establishments exported 8,516,693 pounds of cured pork, canned picnics, luncheon meat, or chopped ham, and pork sausage to the U.S. There were no port-of-entry rejections.

## PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Dutch national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. Establishments 60, 64, 82, 101, 160, 236, and 312 were selected randomly for records audits. The third part involved on-site visits to eight establishments: four slaughter establishments (27, 193, 369, and 378) and four processing establishments (55, 129, 153, and 242) were selected randomly. The fourth was a visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmonella*.

The Netherlands program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials (this was the case with one establishment – Est. 27).

## RESULTS AND DISCUSSION

### Summary

Effective inspection system controls were found to be in place in only six of the eight establishments audited: all of these six establishments (129, 193, 242, 378, 153, and 55) were recommended for re-review. Two establishments (27 and 369) were found to be unacceptable. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

As stated above, numerous major concerns had been identified during the last audit of the Dutch meat inspection system that was conducted in February 2000.

During this new audit, the auditor determined that some of these major concerns had been addressed and corrected by the National Inspection Service for Livestock and Meat (RVV). However, the following deficiencies identified in the February 2000 audit had not been addressed and corrected.

- No adequate daily inspection coverage to processed product establishments and warehouse/freezer facilities. *This was a repeat deficiency.*
- Monthly supervisory visits were not performed. Only two internal reviews were conducted per year by the district or regional auditors. *This was a repeat deficiency.*
- No daily inspection coverage provided for second and third shift operations. *This was a repeat deficiency.*
- Post-mortem inspection procedures for large calves were incomplete. *This was a repeat deficiency.*
- RVV does not have a microbiological monitoring program for finished products, which includes 'scheduled' or 'directed' testing (*Salmonella* and *Listeria*) for ready-to-eat product. *This was a repeat deficiency.*

During this new audit the following deficiencies were noted.

- Implementation of the required HACCP programs was now found to be deficient in all fifteen establishments visited on-site and records audits. Details are provided in the Slaughter/ Processing Controls section later in this report.
- In fourteen establishments, the implementation and maintenance of SSOP was inadequate.
- In seven establishments, there were instances of actual product contamination and instances of the potential for direct product contamination.
- In four establishments, there were inadequate inspection system controls, including the identification of containers for edible and inedible product, enforcement of the zero-tolerance for visible fecal material/ingesta contamination, and milk on carcasses, lack of postmortem inspection procedures to check for disease, and carcass and offal inspection requirements.
- In all of the establishments, there was a lack of periodic supervisory reviews of certified establishments.
- In all establishments producing processed products, GON meat inspection officials were not providing adequate daily inspection coverage. Inspectors were visiting establishments at variable frequencies such as once a week, once a month, four times a year, daily, and between one to four hours each visit.
- In all establishments producing processed products, Government of Netherlands (GON) meat inspection officials were not providing daily inspection coverage for second and third shift operations.
- In all establishments, the final review of all documentation associated with the production of the product prior to shipping was not done.
- In both laboratories (RIKILT and RVV), the quality assurance program, such as check sample programs, was not adequately maintained, there was no documentation for any corrective actions taken when percent recovery results fell below the established

acceptable range limit, and the standards book was not maintained for the quality assurance program.

- Samples for chlorinated hydrocarbons, polychlorinated biphenyls, organophosphates, trace elements, hormones, and nitrogen pesticides were not analyzed in a timely manner. Samples were analyzed and completed between 6 to 12 weeks. It is extremely critical for OP, DES, Sulfonamides, A.B. testing.
- In six establishments, the carcass selection was not made randomly and the random method was not specified in the procedure for the testing of generic *E. coli*.
- In seven establishments, inspectors were not taking samples randomly for *Salmonella* testing.
- RVV does not have a microbiological monitoring program for finished products, which includes 'schedule' or 'directed' testing (*Salmonella* and *Listeria*) for ready-to-eat product.

### Entrance Meeting

On October 1, an entrance meeting with Netherlands government officials was held at the Voorburg offices of the National Inspection Service for Livestock and Meat (RVV). The Dutch government participants were Dr. Tom Akkerman, Deputy Chief Veterinary officer, Ministry of Agriculture, Nature Management and Fisheries (VVM); Dr. Jan-Willem Zijlker, Policy Advisor (VVM); Dr. Jan van den Berg, Deputy Director, National Inspection Service for Livestock and Meat (RVV); Dr. Luuk van Duijn, Head of the Inspection Department (RVV); Dr. Ate Jelsma, Coordinator Inspections (RVV); Dr. Ron Dwinger, Policy Advisor (RVV); Dr. Henk Keukens, Head of RVV Laboratories (RVV); Dr. Willem Droppers, Policy Advisor, Ministry of Health; Mr. Gerke Corstiaensen, Meat Industry Representative, and Mr. J. Klessens, Meat Industry Representative, Central Organization for the Meat Industry (COV).

The United States government participants were Mr. Philip Letarte, Agricultural Counselor, American Embassy, The Hague, and Dr. Faizur R. Choudry, International Audit Staff Officer, Food Safety and Inspection Service (FSIS).

Topics of discussion included the following:

- Welcome by Dr. Tom Akkerman, Deputy Chief Veterinary officer, and explanation of the Dutch meat inspection system.
- Overview of the National Residue Program.
- Discussion of the previous audit report.
- Training programs for veterinary meat inspection officials for pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing
- The audit itinerary and travel arrangements.
- The auditor provided a copy of the current Quarterly Regulatory and Enforcement Report.

## Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Netherlands inspection system in February 2000.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called “the auditor”) observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishments listed for records review. This records review was conducted at the Ministry of Agriculture, Nature Management and Fisheries, National Inspection Service for Livestock and Meat (RVV) office. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

The following concerns arose as a result the examination of these documents.

## HACCP Programs

- In three establishments, the HACCP plan did not adequately conduct a hazard analysis that included food safety hazards likely to occur.
- In six establishments, the HACCP plan did not adequately specify critical limits for each CCP, and the monitoring frequency with which these procedures would be performed.
- In six establishments, the HACCP plan did not address adequately the corrective actions to be followed in response to deviations from critical limits.
- In one establishment, the HACCP plan was not validated to determine that it was functioning as intended.

- In seven establishments, the HACCP plans did not adequately state the procedures that the establishment would use to verify that the plan was being effectively implemented and the frequencies with which these procedures would be performed. The on-going verification activities of the HACCP programs were not adequately performed by establishment personnel.
- In five establishments, the HACCP plan's record-keeping system was not adequately documenting the monitoring of CCPs and/or was not including records with actual values and observations.
- In seven establishments, the final review of all documentation associated with the production of the product prior to shipping was not done.
- In seven establishments, the verification activities of the HACCP plan were not adequately performed by the GON meat inspection officials.

#### Sanitation Standard Operating Procedure (SSOP)

- In one establishment, the written SSOP did not address operational sanitation.
- In five establishments, the daily monitoring records of pre-operational and operational sanitation and any corrective actions taken were not being adequately maintained.
- GON meat inspection officials were only monitoring/verifying the adequacy and effectiveness of pre-operational sanitation at variable frequencies such as daily, twice a week and monthly, and records of these activities were not adequately maintained.

#### Testing for Generic *E.coli*

- In three establishments, the carcass selection was not made randomly and the random method was not specified in the procedure.

#### Inspection System Controls

- GON meat inspection officials were not providing adequate daily inspection coverage to processing establishments. Inspectors were visiting establishments once a month and for only two or three hours per visit in two establishments.
- In seven establishments, the monthly supervisory visits were not performed. Only two internal reviews were conducted per year by the district or regional auditors.
- In four establishments, the carcass selection for *Salmonella* testing was not made randomly by the GON meat inspection officials.

#### Government Oversight

All inspection veterinarians and inspectors in establishments certified by the Netherlands as eligible to export meat products to the United States were full-time or some part-time National Inspection Service for Livestock and Meat (RVV) employees of the Ministry of Agriculture, Nature Management and Fisheries, receiving no remuneration from either industry or establishment personnel.

The most relevant responsibilities of the central government are to participate and negotiate during new or revised EC legislation, to interpret and clarify EC Directives and federal laws and regulations, to ensure implementation, and to pass these documents on to the five regional departments. These are then passed on to the districts and to the team leader by the district offices. These regional departments are split into seventeen districts (each region between 3 to 4 districts) and these districts are split into forty-nine teams (each district between 3 to 4 teams). Each team has a team leader and the team consists of between twenty-five and forty employees which includes veterinarians and non-veterinarians inspectors. Each team is responsible for carrying out inspection and control tasks in their assigned slaughter and processed products establishments. Several auditors are assigned in the districts and in some regions and they are responsible for carrying out two audits at every establishment yearly.

All inspection compliance is mandated by the central government and carried out by the regional and district offices. The audit report is kept in the archives of the official veterinarian, district and regional offices. The management of the establishment receives a copy of the report. The follow-up audit was carried out by a team of auditors.

However, in relation to daily supervision, corrective actions were not adequately followed-up. Although in most establishments, serious pre-operational and operational sanitation deficiencies were revealed.

The supervision and authority is established or delegated by the central government. The region, district, team leader and official veterinarian in the establishments that work within these levels of authority are accountable to the central government. Disciplining or firing resident veterinarians or inspectors is recommended by the team leader to district office to region and to the central government.

Although there are detailed instructions of what to do when visiting a “lower” level authority, including visits to an establishment, the central governments rely heavily upon the results of region, district audits of their inspection system.

In addition, part of the responsibility of the region and district is to approve establishments for EC and U.S. markets and to withdraw federal approval from these establishments. The district office notifies the regional office and to the central government office in The Hague of each approval and withdrawal. The central government office normally does not visit these establishments as a result of the approval and does not supervise or question the validity of a region’s, district’s decision to approve or withdraw an establishment. However, the districts work closely with the team leader and auditor to secure compliance for the approvals and have extensive documentation of their pre-approval inspections of the establishments.

### Establishment Audits

Twenty-four establishments were certified to export meat products to the United States at the time this audit was conducted. Eight establishments (27, 129, 193, 369, 242, 378, 153,

and 55) were visited for on-site audits. In six of the eight establishments visited, both Netherlands inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products, however these six establishments (129, 193, 242, 378, 153, and 55) were rated acceptable re-review because of deficiencies regarding sanitation, condition of facilities, and non-compliance with HACCP requirements.

Two establishments (27 and 369) were found to be unacceptable because of critical sanitation problems and findings of direct product contamination.

### Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories. Intra-laboratory quality assurance procedures, including sample handling and methodology.

The State Institute for Quality Control of Agricultural Products Laboratory (RIKILT) in Wageningen was audited on October 17, 2001. Except as noted below, effective controls were in place for sample handling and frequency, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, and recovery frequency. The methods used for the analyses were acceptable. No compositing of samples was done.

The following deficiencies were noted:

- The check samples program did not meet FSIS requirements. In most sections of the laboratory, regular spiked samples that were routinely run as part of a sample set were erroneously considered to be check samples. No check samples were performed for chlorinated hydrocarbons, polychlorinated biphenyls, organophosphates, trace elements, and nitrogen pesticides
- Samples for chlorinated hydrocarbons, polychlorinated biphenyls, organophosphates, trace elements, hormones, and nitrogen pesticides were not analyzed in a timely manner such as samples were analyzed and completed between 6 to 12 weeks.
- Standards book for organophosphates, trace elements, and nitrogen pesticides was not maintained for quality assurance program.
- When percent recovery results were fallen below the established acceptable range limit and any corrective actions taken were not documented for quality assurance program such as hexachlorobenzene, methomyl, and propoxur.

Netherlands microbiological testing for *Salmonella* was being performed in government laboratories. One of these, the Laboratory of the Inspection Service for Livestock and Meat (LRVV) in Wageningen, was audited on October 19, 2001.



The following deficiencies were noted:

- The standards book for hormones was not maintained for the quality assurance program.
- When percent recovery results fell below the established acceptable range limit and any corrective actions taken were not documented for quality assurance program such as sulfadimethoxine and hormones.

#### Establishment Operations by Establishment Number

The following operations were being conducted in the eight establishments:

Pork slaughter and boning - four establishments (27, 193, and 378)

Pork boning and canning – four establishments (129, 242, 153, and 55)

Veal slaughter and boning – one establishment (369)

#### SANITATION CONTROLS

Based on the on-site audits of establishments, Netherlands inspection system had controls in place for water potability records; chlorination procedures; back-siphonage prevention; hand washing facilities; pest control monitoring; separation of operations; temperature control; work space; ventilation, ante-mortem facilities; welfare facilities; outside premises; and personal dress and habits.

The auditor's findings are presented below for the areas of SSOP, cross-contamination, product handling and storage, product reconditioning, and personal hygiene and practices.

#### Sanitation Standard Operating Procedures (SSOP)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs in the eight establishments were found to meet the basic FSIS regulatory requirements with the following deficiencies.

- In all establishments, the written SSOP procedure did not adequately address pre-operational sanitation.
- In all establishments, the written SSOPs did not adequately address operational sanitation.
- In one establishment, the SSOP procedure did not identify the individual responsible for implementing and maintaining the activities.
- In all establishments, the daily pre-operational and operational sanitation deficiencies were not identified most of the time and any corrective actions taken were not adequately documented by the establishment personnel.

Cross-Contamination: In the area of cross-contamination, actual product contamination and the potential for product contamination was found in seven out of the eight establishments audited. In some establishments, but not all, the GON took corrective actions. Specific findings for each establishment audited on-site can be found in Attachment F.

Examples of findings of actual product contamination include:

- In five establishments, dripping condensate, from overhead refrigeration units, ceilings, pipes, beams, ducts, exhaust system, deteriorated and broken insulation on ducts that were not cleaned/sanitized daily, was falling onto carcasses and exposed edible product in the slaughter room, coolers, boning rooms, and processing rooms.
- In two establishments, sanitizers were not maintained at the required temperature (82° C) in the boning rooms during the operation. In another two establishments, there was no sanitizing facility for knives and the circular saw in the cut-up and boning rooms. In one of these establishments, the automatic hog carcass splitting saw was not sanitized completely and effectively between each use in the slaughter room. In two establishments, automatic viscera and offal conveyors were not sanitized in the slaughter room. In two establishments, knives were not sanitized between each use during sticking operations.
- In one establishment, the automatic viscera conveyor and offal hook conveyor in the slaughter room were soiled with blood and fat after washing/sanitizing in the slaughter room. In three establishments, hog and calf carcasses were contacting employees' working platforms and employees' boots, stands, container for inedible products, automatic dirty hide removal in the slaughter rooms. In one of these establishments, numerous calf carcasses were dragging along the floor in the slaughter, coolers, hallway and cut-up rooms and in the same establishment removal of dirt and extraneous materials from hind quarters with vacuum was not being done in a sanitary manner.
- In six establishments, insanitary equipment was directly contacting edible product in the processing rooms, offal rooms, boning rooms, and slaughter rooms. For example, containers of edible product, meat hooks, meat racks, employees' scabbards, tumblers, and container for brine solution were found with fat, dried pieces of meat, blood, dirt, grease, black discoloration and detergent residue from previous days' operations.

Examples of findings of potential cross-contamination of product include:

- In one establishment, employees were crossing over unprotected conveyor belts for edible products in the cut-up room. In another establishment, containers of edible product were kept too close to a hand washing facility creating the potential for the splashing of dirty water during hand washing; dirty unskinned tails were swinging heavily over exposed carcasses after hide removal station creating the potential for dirt and fecal contamination.
- In three establishments, overhead pipes, beams, lights, and protective coverings in the slaughter and processing rooms were observed with accumulations of fat, old pieces of meat, dirt, dust, grease, and mold.
- In five establishments, several employees were observed picking up dirty objects from the floor, handling containers of inedible product, using a dirty steel and a meat scrapper which were kept in the sink, handling dirty pallets, picking up pieces of meat from the

floor and, without washing their hands and washing/sanitizing dirty equipment, handling edible product.

**Product Handling and Storage:** In the area of product handling and storage, the following deficiencies were found. Establishment officials took corrective actions.

- In one establishment, carcasses were found with grease, hair, pieces of hide, and fecal materials in the coolers and, in the same establishment, carcasses were found with grease, hair, pieces of hide after pre-boning trim in the boning room.
- In one establishment, exposed edible product was contacting dirty pallets in the meat grinding room.
- In three establishments, product that contacted the floor (dropped meat) was not reconditioned in a sanitary manner before being added to the edible product such as: several pieces of dropped meat and pieces of meat with abscesses were collected in the same container for trimming; some employees were only scrapping contamination from meat or singeing meat with a gas torch instead of trimming.
- In three establishments, containers for edible and inedible product were not identified to prevent possible cross contamination.
- In two establishments, pest control prevention was inadequate. For example, in both establishments, gaps at the bottoms of doors in the dry storage and shipping rooms were not sealed properly to prevent the entry of rodents and other vermin. In one of these establishments, there was no air-curtain or other device on the door in the offal room to prevent the entry of insects and other vermin. Establishment officials ordered correction.

## **ANIMAL DISEASE CONTROLS**

The Netherlands inspection system had controls in place to ensure adequate animal identification, ante-mortem and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework products.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit. In addition, the Netherlands is not declared free from hog cholera disease by APHIS, although OIE has declared Netherlands free of hog cholera disease. The U.S. does not import any beef from the Netherlands

## **RESIDUE CONTROLS**

The Netherlands National Residue Testing Plan for 2000 was being followed, and was on schedule. The Dutch inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

### Farm Visit

The Verbeek farm, located in Ubbeschoterweg 8A, 3927 CJ, Renswoude, was visited on October 18, 2001. It is a small swine-breeding farm on a thirteen-hectare land with about 1750 sows and boar including market hogs.

A full time private veterinarian makes the diagnosis, writes the prescription and administers the drugs for treatment. Animals are identified by a single earmark, which identifies the farm, as well as a tattooing mark before leaving farm, the month of the birth of the animal and the code for the farm (premises). Medicated feeds are not given to sows, boars and young pigs or breeding stock on this farm.

General Inspection Service (AID) is required to analyze one sample of feed each year to demonstrate that feed is not medicated and if there is any doubt then the feed delivery company is required to take more samples. In the Netherlands, sixty percent of farmers are not using medicated feeds.

The swine farm that was visited is licensed to store animal drugs on site. Farms must be specifically approved to store animal drugs on the premises. On those farms which are not approved to store drugs, the veterinarian may only prescribe drugs in amounts that can be used immediately. Records are maintained on all animal drugs requiring prescription, which are written in duplicate so that copies can be maintained by the prescribing veterinarian and filed at the farm. The General Inspection Service officials cross check and verify all the prescriptions written or dispensed on the farm three times a year.

Certificates (affidavits) are issued for every group of animals moving off of the farm, whether to another farm or to slaughter. Any drugs applied to animals within 75 days of slaughter will be recorded on the transportation documents, with a copy of the prescription attached. Drug inventory and use records are maintained and all drugs are controlled in a locked cabinet or refrigerator.

The National Program for Residue Control is based on European Community legislation in force related to the ban of hormonal substances (Council Directive 96/22/EC April 1996) and the control of residues on live animals and animal products (Council Directive 96/23/EC of April 1996).

### Reporting Positive Results

Though no violations had occurred at the farm visited, the Regional authorities confirmed that violations are followed up on a case-by-case approach, depending upon the substance in question. At the farm, the General Inspection Service (AID) will increase inspections but may not take a sample every time. If animal samples are found to be positive, the AID launches an investigation into the cause. Animals from which positive samples are taken are seized and destroyed. In case of illegal growth promoters additional sampling must be carried out. The number of animals to be sampled equals the root + 1 of the number of animals present. If positive samples are subsequently detected in one or more animals, all

the animals present on the holding must be sampled. Only those animals from which positive samples are taken are destroyed. Fines can be imposed as a penalty.

## SLAUGHTER/PROCESSING CONTROLS

Except as noted below, the Dutch inspection system had controls in place to ensure adequate animal identification; antemortem inspection procedures; antemortem disposition; humane slaughter; postmortem dispositions; restricted product control; ingredients identification; control of restricted ingredients; formulations; packaging materials; label approvals; inspector monitoring; processing equipment; processing records; empty can inspection; filling procedures; container closure examination; and post-processing handling.

### HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were reviewed during the on-site audits of eight establishments. The auditor found the following deviations from FSIS regulatory requirements.

- In two establishments, the HACCP plan did not have a flow chart that describes the process steps and product flow.
- In four establishments, the HACCP plan did not adequately conduct a hazard analysis.
- In eight establishments, the HACCP plan did not specify critical limits for each CCP and the frequency with which these procedures would be performed.
- In eight establishments, the HACCP plan did not address adequately the corrective actions to be followed in response to deviations from critical limits.
- In eight establishments, the HACCP plan was not validated to determine if it was functioning as intended.
- In eight establishments, the HACCP plan did not adequately state the procedures that the establishment would use to verify that the plan was being effectively implemented and the frequencies with which these procedures would be performed. The on-going verification activities of the HACCP program were not adequately performed either by the establishment personnel or by the GON meat inspection officials.
- In eight establishments, the HACCP plan's record keeping system was not documenting the monitoring of CCPs.
- In eight establishments, the final review of all documentation associated with the production of the product prior to shipping was not done.

### Testing for Generic *E. coli*

The Netherlands has adopted the FSIS regulatory requirements for generic *E. coli* testing with the exception of the following equivalent measures. Four of the eight establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing. These four establishments were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

#### 1. INDICATOR MICROORGANISM: Different Organism.

- The Netherlands uses Enterobacteriaceae as its indicator organism. This microorganism is an indicator for fecal contamination.
- The microorganism is as sensitive as generic *E. coli* in measuring the control of fecal contamination throughout the slaughter and dressing operations.

#### 2. GENERIC *E. COLI* TESTING STRATEGY:

- Testing frequency is ten tests per week.
- The predominant class of animals slaughtered in an establishment is sampled.

#### 3. SAMPLING SITES:

- The Netherlands samples swine at four sites: flank, brisket, rump, and back. The sample sites include the sites most likely to be contaminated with fecal contamination.
- The sample sites encompass a large enough surface area to ensure that the effectiveness of the slaughter process controls will be evaluated.
- The sample sites provide the same probability of detecting the presence of fecal contamination as the sites chosen by FSIS.

#### 4. SAMPLING TOOL

- The Netherlands uses a cork borer-sampling tool. The cork borer is a traditional or generally recognized sample collection tool for sampling for *E. coli* on meat or poultry surfaces.
- The tool is sensitive enough to gather *E. coli* present on the sample site.
- The tool does not contaminate the surfaces of the carcass.

The following deficiencies were noted.

- In one establishment, the procedure did not designate the employee(s) responsible for collecting the samples.
- In one establishment, the procedures did not designate the establishment location for sample collecting.
- In three establishments, the carcass selection was not made randomly and the random method was not specified in the procedure.

Additionally, establishments had adequate controls in place to prevent meat products intended for Netherlands domestic consumption from being commingled with products eligible for export to the U.S.

## ENFORCEMENT CONTROLS

### Inspection System Controls

Except as noted below, and with the exception of the unacceptable establishments (27 and 369), the Dutch inspection system controls [ante-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls, and documentation, the importation of only eligible livestock from other countries (i.e., only from eligible countries and certified establishments within those countries), were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

### Testing for *Salmonella* Species

Four of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The Netherlands has adopted the FSIS regulatory requirements for *Salmonella* testing with exception of the following equivalent measures. However, for the testing of carcasses for the presence of *Salmonella*, the sponge method, and not the corkbore method, is used in the targeted and screening analysis.

#### 1. SALMONELLA TESTING STRATEGY.

- The Netherlands uses a continuous, on-going sampling program to determine when to initiate additional *Salmonella* testing. All U.S. export establishments are included in the same pool. The sampling methodology is based on a uniform system approach in all applicable export establishments. Following an initial sample set in each applicable establishment; continuous sampling is used to initiate additional *Salmonella* testing. The on-going sampling program used in the four “small” establishments occurs at a rate of one sample every 4 weeks
- Three consecutive positive screenings initiates the Target Program.

- The Target Program is identical to FSIS program except that it is automatically initiated every 3 years, unless positive results are found. Sampling is thereby tightened, as stated below.
- After a screening failure, if standard is met after 1<sup>st</sup> set: target program, sampling is re-initiated in two years. (2) If 1<sup>st</sup> set fails but 2<sup>nd</sup> set meets the standard, sampling is re-initiated in two years. (3) If 2<sup>nd</sup> set fails but 3<sup>rd</sup> set meets the standard, sampling is re-initiated the following year.
- The Netherlands uses a continuous, on-going sampling program to determine when to initiate additional *Salmonella* testing. All products for which there is a U.S. performance standard are included in the sample pool.
- The Netherlands testing program has statistical criteria for evaluating test results.
- The percentage of *Salmonella* positives over time meets the FSIS performance standard.

## 2. SAMPLING TOOLS.

- The Netherlands uses a cork borer-sampling tool. The cork borer is a traditional or an internationally recognized sample collection tool for sampling *Salmonella* on meat or poultry product surfaces.
- The sampling tool is sensitive enough to gather *Salmonella* that are present at the sample site.
- The sampling tool does not contaminate the surfaces of the carcass.

### 1. SAMPLING TECHNIQUES: Time of collection.

- Samples are taken at the end of the slaughter or production process.
- Samples are taken prior to the carcass being cut and/or packaged.

### 2. SAMPLING TECHNIQUES: Depth of excision.

- The Netherlands uses the cork-borer method to collect samples and the method excises tissue to a depth of 2.5 mm. The cork-borer method collects all surfaces area *Salmonella* from the tissues excised without contaminating the carcass.

### 3. SAMPLING TECHNIQUES: Compositing Samples.

- Samples are “composited” in the same whirl –pack at the sample sit. Each entire collection-site that is sampled (i.e. the sample tissue area) is included in the composite sample and the entire composite is analyzed for *Salmonella*.
- The sample sites include the sample collection area from all three FSIS sample sites.

### 4. ANALYTICAL METHODS: Different Methods.

- The laboratories use ISO 6579 to analyze for *Salmonella*. ISO 6579 is an internationally recognized method of analysis for detecting *Salmonella* and is closer to the FSIS method than the AOAC methods.



## 5. LOCATION AND SIZE OF SAMPLE SITES:

- Sampling is accomplished by boring 4/5 inch<sup>2</sup> bores per site. The cork-borer method is capable of collecting all of the surface *Salmonella* at each sample site. This method collects 20 cm<sup>2</sup> from each FSIS designated site, resulting in a composite sample of 60 cm<sup>2</sup>.
- The sample size and sites provide the same probability of detecting the presence of *Salmonella* as the FSIS sample sites.

The following deficiencies were noted.

- In three establishments, the samples were not being taken randomly.

### Species Verification Testing

At the time of this audit, the Netherlands was not exempt from the species verification-testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

- Species verification testing is not carried out by the National Inspection Service for Livestock and Meat (RVV) officials as required.

### *Listeria monocytogenes*

- The control of *Listeria monocytogenes* is not included in the HACCP plan in establishments producing ready-to-eat products.
- Establishment officials have a surveillance program for *Listeria monocytogenes* testing at variable frequencies of sampling such as per week/month and/or per year in establishments producing ready-to-eat products. The RVV meat inspection service was taking between five to ten samples per year for *Listeria monocytogenes*.

### Monthly Reviews

The internal review program was applied equally to both export and non-export establishments. Internal review visits were not announced in advance, and were conducted, at times by individuals and at other times by a team of reviewers, twice a year. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the district or regional offices, and were routinely maintained on file for a minimum of two years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, a team of auditors is empowered to conduct an in-

depth review, and the results are reported to district and region for evaluation; they formulate a plan for corrective actions and preventive measures.

The following deficiencies were noted.

- In all eight establishments, monthly supervisory visits were not performed. Only two internal reviews were conducted per year by the district or regional auditors.
- In all establishments producing processed products, GON meat inspection officials were not providing adequate daily inspection coverage. Inspectors were visiting establishments at variable frequencies such as once a week, once a month, four times a year, daily, and between one to four hours each visit.
- In all establishments producing processed products, GON meat inspection officials were not providing daily inspection coverage for second and third shift operations.

### Enforcement Activities

Controls were in place to ensure adequate export product identification, inspector verification, export certificates, a single standard of control throughout the establishment, and adequate controls for security items, shipment security, and products entering the establishments from outside sources.

Enforcement activities are carried out by district/regional officials, which have full power to initiate all enforcement actions.

### Inspection system Controls

- In two establishments, inspectors were not correctly performing post-mortem inspection procedures such as: large calves the lateral masticatory muscles on head were not properly incised and observed; the medial masticatory muscles were not incised; the lymph nodes of head, liver, and lungs were not incised and observed; the mandibular lymph nodes of swine heads were not properly incised and observed, and the liver, lungs, and mesenteric lymph nodes were not palpated as required. GON inspection officials did not take any corrective action.
- In one establishment, post-mortem inspection correlation between hog carcass and viscera was not maintained such as: one carcass dropped on the floor prior to inspection and the viscera for that carcass was not retained for proper post-mortem inspection.
- In four establishments, the zero tolerance for visible fecal material/ ingesta contamination, and milk on carcasses was not enforced by the GON meat inspection officials, and there was no monitoring record maintained to verify this activity.
- In three establishments, containers for edible and inedible product were not identified to prevent possible product cross contamination.

## Exit Meetings

On October 23, 2001, an exit meeting with the Netherlands government officials was held at the Voorburg offices of the National Inspection Service for Livestock and Meat (RVV). The Dutch government participants were Dr. Jan van den Berg, Deputy Director, National Inspection Service for Livestock and Meat (RVV); Dr. Luuk van Duijn, Head of the Inspection Department (LNV); Dr. Ron Dwinger, Policy Advisor (LNV); Dr. Henk Keukens, Head of RVV Laboratories (LNV); Dr. Jan Bloemendal, Policy Advisor, Ministry of Agriculture, Nature Management and Fisheries (VVM); Dr. J. Peelen, South Regional Director (RVV); Dr. J. Haverkort, East Regional Director (RVV); Dr. M. T. Ijzerman, District Head, North Region (RVV); and Mr. Gerke Corstiaensen, Meat Industry Representative. The United States government participants were Mr. Bob Flach, Agricultural Specialist, American Embassy, The Hague, and Dr. Faizur R. Choudry, International Audit Staff Officer, Food Safety and Inspection Service (FSIS).

A second meeting was conducted with the European Commission (EC) in Brussels, Belgium on October 24, 2001. The EC participants were Dr. Paolo Dhostby, DG, Health and Consumer Protection Directorate General (SANCO), Unit E-3. The Dutch government participants were Dr. Jan Bloemendal, Dr. Luuk van Duijn, Dr. Ron Dwinger and Dr. Star Van der Meijs, Veterinary board at the Dutch Embassy for the EU in Brussels. The participants from the United States were Ms. Sally Stratmoen, Chief, Equivalence, International Policy Staff, FSIS (by telephone); Dr. Faizur R. Choudry, International Audit Staff Officer, FSIS; Ms. Melinda D. Sallyards, Agricultural Attaché, United States Mission to the European Union, Foreign Agricultural Service, Brussels.

The auditor explained to the GON inspection officials that their inspection system was audited in accordance with the European Union/United States Veterinary Equivalence Agreement, the auditors audited the meat inspection system using European Directives, specifically Council Directives 96/23/EC of April 29, 1996, 96/22/EC of April 29, 1996, and 64/433/EEC of June 1964. These three directives have been declared equivalent under the Agreement. In areas not covered by these directives, the auditors audited against FSIS requirements and equivalence determinations.

The following topics were discussed:

- The continuing problems with the implementation and maintenance of SSOP in certified establishments.
- The continuing problems with implementation and maintenance of HACCP systems in certified establishments.
- Instances of actual product contamination and instances of the potential for direct product contamination.
- Inadequate inspection system controls, including the identification of containers for edible and inedible product, enforcement of the zero-tolerance policy for visible fecal material/ingesta contamination, and milk on carcasses, lack of post-mortem inspection procedures to check for disease, and carcass and offal inspection requirements.

- The lack of adequate daily inspection coverage in establishments producing products for export to the U.S.
- The lack of periodic supervisory reviews of certified establishments.
- The lack of daily inspection coverage for second and third shift operations of processing establishments.
- In all establishments, the final review of all documentation associated with the production of the product prior to shipping was not done.
- In both laboratories (RIKILT and RVV), the quality assurance program was not adequately maintained such as check samples programs, there was no documentation for any corrective actions taken when percent recovery results fell below the established acceptable range limit, and the standards book was not maintained for quality assurance program.
- Timely analyses, samples for chlorinated hydrocarbons, polychlorinated biphenyls, organophosphates, trace elements, hormones, and nitrogen pesticides were not analyzed in a timely manner such as samples were analyzed and completed between 6 to 12 weeks. This is extremely critical for OP, DES, Sulfonamides, and A.B. testing.
- In six establishments, the carcass selection was not made randomly and the random method was not specified in the procedure for the testing of generic *E. coli*.
- In seven establishments, inspectors were not taking samples randomly for *Salmonella* testing.
- RVV does not have a microbiological monitoring program for finished products, which includes 'scheduled' or 'directed' testing (*Salmonella* and *Listeria*) for ready-to-eat product.

Dr. Jan van den Berg, Deputy Director, (RVV), stated that he would take the necessary steps to ensure that corrective actions and preventive measures, including HACCP, SSOP, sanitation problems, and monthly visits as promised during the audits and exit meetings in the individual establishments would be implemented.

## CONCLUSION

The Dutch meat inspection system has major deficiencies, which demonstrates a lack of government oversight as evidenced by the findings presented in this report and summarized below.

Eight establishments were audited: six were evaluated as acceptable/re-review, and two were unacceptable. The GON meat inspection officials reinforced the assurances made by the field personnel during and at the conclusions of the on-site audits of the establishments, and stated that they would ensure prompt compliance. However, these assurances have been given previously at the conclusion of the February 1999 and February 2000 audits, and some corrective actions taken were not adequate.

Dr. Faizur R. Choudry  
International Audit Staff Officer

(signed) Dr. Faizur R. Choudry

## ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing.
- D. Data collection instrument for *Salmonella* testing
- E. Laboratory Audit Forms
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report

### Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
27	√	no	no	√	√	√	no	√
129	√	no	no	√	√	√	no	√
193	√	no	no	√	√	√	no	√
369	√	no	no	√	√	√	no	√
378	√	no	no	√	√	√	no	√
242	√	no	no	√	√	√	no	√
153	√	no	no	√	√	no	no	√
55	√	no	no	√	√	√	no	√

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

60	√	√	√	√	√	√	no	√
64	√	√	√	√	√	√	no	√
101	√	√	no	√	√	√	no	√
82	√	√	√	√	√	√	√	√
312	√	√	√	√	√	√	√	√
160	√	√	√	√	√	√	no	√
236	√	√	√	√	√	√	no	√

### Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment doc. review
27	√	no	√	√	√	no	no	no	no	no	√	no
129	√	no	√	√	√	no	no	no	no	no	√	no
193	√	√	√	√	√	no	no	no	no	no	√	no
369	√	√	√	√	√	no	no	no	no	no	√	no
378	√	no	√	√	√	no	no	no	no	no	√	no
242	no	no	√	√	√	no	no	no	no	no	√	no
153	no	√	√	√	√	no	no	no	no	no	√	no
55	√	√	√	√	√	no	no	no	no	no	√	no

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment doc. review
60	√	√	√	√	√	no	no	√	no	√	√	no
64	√	no	√	√	√	no	no	√	no	no	√	no
101	√	√	√	√	√	no	no	√	no	no	√	no
82	√	√	√	√	√	√	√	√	no	√	√	no
312	√	no	√	√	√	no	no	√	no	no	√	no
160	√	√	√	√	√	no	no	√	no	no	√	no
236	√	no	√	√	√	no	no	no	no	no	√	no



### Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1. Writ-ten pro-cedure	2. Samp-ler des-ignated	3. Samp-ling lo-cation given	4. Pre-domin. species sampled	5. Samp-ling at the req'd freq.	6. Pro-per site or method	7. Samp-ling is random	8. Using AOAC method	9. Chart or graph of results	10. Re-sults are kept at least 1 yr
27	√	no	√	√	√	√	no	√	√	√
193	√	√	√	√	√	√	√	√	√	√
369	√	√	√	√	√	√	no	√	√	√
378	√	√	no	√	√	√	no	√	√	√

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

60	√	√	√	√	√	√	no	√	√	√
64	√	√	√	√	√	√	√	√	√	√
312	√	√	√	√	√	√	no	√	√	√
236	√	√	√	√	√	√	no	√		√
160	√	√	√	√	√	√	√	√	√	√

### Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
27	√	√	N/A	no	√	√
193	√	√	N/A	no	√	√
369	√	√	N/A	√	√	√
378	√	√	N/A	no	√	√

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

60	√	√	N/A	no	√	√
64	√	√	N/A	no	√	√
312	√	√	N/A	no	√	√
236	√	√	N/A	√	√	√
160	√	√	N/A	no	√	√